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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/346,479 07/01/99 RITTER

A 4806-2

EXAMINER

HM22/0308

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COE, S

ART UNIT	PAPER NUMBER
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1651

DATE MAILED:

03/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/346,479

Applicant(s)

RITTER, ANDREW J.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☒ Interview Summary (PTO-413) Paper No(s). 3.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. The amendment filed December 29, 2000, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.
2. Claims 1-24 have been cancelled.
3. Claims 25-48 have been added.
4. Claims 25-48 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 25 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (Journal of Dairy Science (1983), vol. 66, pp. 959-966).

The claims are drawn to a method of reducing lactose intolerance by administering a lactose product concurrently with a fermented dairy product that contains live bacteria.

Kim teaches that administering milk with added *Lactobacillus acidophilus* increases lactose tolerance in subjects that are lactose intolerant. The subjects consuming the milk with added *L. acidophilus* showed a large improvement in the toleration of lactose (see Table 2 on page 962 and Table 3 on page 963).

From applicant's remarks, it appears that the lactose containing product and the fermented product containing the bacteria are intended to be different products. However, the claims do not clearly reflect this limitation. Milk is a lactose containing product; thus, drinking milk with live bacteria is considered to anticipate the claims because the lactose is being administered with the fermented dairy product. The milk is fermented by the *L. acidophilus* cultures.

6. Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Onwulata (Am. J. Clin. Nutr. (1989), vol. 49, pp. 1233-1237).

The claims are drawn to a method of reducing lactose intolerance by administering a lactose product concurrently with a fermented dairy product that contains live bacteria.

Onwulata teaches that administering yogurt increases lactose tolerance in lactose intolerant individuals. The yogurt contained live culture of *L. bulgaricus* and *S. thermophilus*. Therefore, Onwulata shows that it was known in the art at the time of the invention that administering bacteria in conjunction with a lactose containing product, yogurt, increased lactose tolerance.

From applicant's remarks, it appears that the lactose containing product and the fermented product containing the bacteria are intended to be different products. However, the claims do not clearly reflect this limitation. Yogurt is a lactose containing product; thus, eating yogurt with live bacteria is considered to anticipate the claims because the lactose is being administered with the fermented dairy product.

7. Claims 25-28, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Martini et al. (Am. J. Clin. Nutr. (1991), vol. 53, pp. 1253-1258).

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Martini teaches a method of reducing lactose intolerance by administering yogurt with additional lactose or milk (see page 1254, first column, second paragraph).

Claim Rejections - 35 USC § 103

8. Claims 25 and 34-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Journal of Dairy Science (1983), vol. 66, pp. 959-966).

As stated above, Kim teaches that administering milk with added *Lactobacillus acidophilus* increases lactose tolerance in subjects that are lactose intolerant. However, Kim does not teach administering *L. acidophilus* and milk using the regimen claimed by applicant.

The treatment regimen used to treat a disorder is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal dosage schedule and dosage amounts in order to achieve the greatest amount of lactose tolerance. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of treatment regimen would have been obvious at the time of applicant's invention.

9. Claims 25, 29-31, and 34-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onwulata et al. (Am. J. Clin. Nutr (1989), vol. 49, pp. 1233-1237).

As stated above, Onwulata teaches that administering yogurt increases lactose tolerance in lactose intolerant individuals. The yogurt contained live culture of *L. bulgaricus* and *S. thermophilus*. Therefore, Onwulata shows that it was known in the art at the time of the invention that administering bacteria in conjunction with a lactose containing product, yogurt,

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increased lactose tolerance. However, Onwulata does not teach administering yogurt using the regimen claimed by applicant.

The treatment regimen used to treat a disorder is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal dosage schedule and dosage amounts in order to achieve the greatest amount of lactose tolerance. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of treatment regimen would have been obvious at the time of applicant's invention.

10. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 7:30 to 5:00 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
March 5, 2001


FRANCISCO PRATS
PRIMARY EXAMINER